



ARK:jsg060804/6711002CIP-3.REQ

AF
IFW 1723

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant : William J. Schmidt
Serial No. : 09/385,405
Filed : August 30, 1999
For : METHOD FOR THE PURIFICATION AND
RECOVERY OF WASTE GELATIN
Examiner : Robert J. Popovics
Art Unit : 1723
Attorney Docket No. : 671.1.002 CIP-3

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450

ON June 10, 2004

NAME Jill S. Garretson

SIGNATURE

Jill S. Garretson

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

June 10, 2004

REQUEST FOR REINSTATEMENT OF BRIEF ON APPEAL

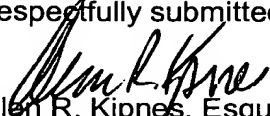
Dear Sir:

Responsive to the Notice of May 12, 2004, Applicant encloses herewith a revised Brief on Appeal to reflect an update of the background of the application and a direct traverse of the prior art rejection based on the combination on Schmidt et al. (U.S. Patent No. 5,288,408) and Dutre et al. Entry and consideration of the Brief on Appeal is deemed proper and is respectfully requested.

ARK:jsg060804/6711002CIP-3.REQ

It is believed that no fee is due with this request for reinstatement. However, if any fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,


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ON	June 10, 2004
NAME (PRINT)	Jill S. Garretson
SIGNATURE	<i>Jill S. Garretson</i>

Mail Stop Appeal Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

June 10, 2004

BRIEF ON APPEAL

Dear Sir:

Applicant submits herewith pursuant to 37 C.F.R. 1.192(a) a Brief In Triplicate pursuant to the format set forth in 37 C.F.R. 1.192(c). A check in the amount of \$320 is enclosed to cover the Official Fee. Applicants have filed concurrently herewith a Petition for a two month extension of time along with the requisite fee extending the

The PTO did not receive the following listed Items(s) <i>No Check.</i>	-1-
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date for filing Brief to at least December 20, 2002. Any additional fees or credit for overpayment should be charged to Deposit Account No. 23-0510.

(1) Real Party In Interest:

All right, title and interest in and to the present application was assigned from the inventor William J. Schmidt to A.B. Technologies, L.L.C. by Assignment executed on January 10, 2000 and recorded on March 6, 2000 on Reel 010593/Frame 0005. A further Assignment from A.B. Technologies, L.L.C. to A.B. Technologies Holding, L.L.C. was executed on May 23, 2000 and recorded on June 16, 2000 on Reel 010924/Frame 0387

(2) Related Appeals And Interferences:

There are no related appeals or interferences.

(3) Status Of The Claims:

Claims 71-83 are the appealed claims and are set forth in Section (8) herein.

(4) Background Of Application:

The present application was filed on August 30, 1999 under Serial No. 09/385,405 with original claims 1-27. A Preliminary Amendment was filed on November 5, 1999 adding claims 28-43. An Office Action issued on December 1, 1999 setting forth a restriction requirement in which claims 28-43 were withdrawn from further

ARK:jsg060804/6711002CIP-3.BOA

consideration while claims 1-27 were rejected on substantive grounds under 35 U.S.C. § 102 and 103 citing Schmidt et al. (U.S. Patent No. 5,288,408) and provisionally under the judicially created doctrine of obvious type double patenting. A Terminal Disclaimer to overcome the double patenting rejection was filed on March 1, 2000. An Amendment was also filed on March 1, 2000 canceling claims 6, 9 and 28-43 and amending claims 1, 7, 10, 11, 13, 14 and 18. New claims 44-70 were added to the application at this time. A further non-final Office Action issued on June 2, 2000 rejecting the claims in view of Schmidt et al. (the '408 Patent) in combination with any of Fane et al. and Dutre et al. or Chakravorty et al. which was responded to on November 1, 2000 by canceling claim 45 and amending claims 1, 11, 13, 14, 18, 19, 23, 44, 49-52, 56, 57, 64 and 70.

A final Office Action issued on January 31, 2001 in which the claims were rejected as obvious under 35 U.S.C. Section 103(a) over the same references cited in the June 2, 2000 Office Action including Schmidt et al. and Dutre et al. An Examiner Interview followed on February 26, 2001. An Amendment in response to the final Office Action was filed on March 28, 2001 in which claims 5, 11, 12, 18, 20 and 46-69 were canceled and claims 1, 7, 8, 14, 21, 25, 26, 44, 59, 69 and 70 were amended. An advisory Action issued on May 1, 2001 refusing to enter the Amendment of March 28, 2001. A telephonic interview was conducted with the Examiner on May 10, 2001 without agreement.

On July 30, 2001 Applicant responded again to the final Office Action including arguments submitted with respect to all prior art including the Fain et al, Dutre et al. and Chakravorty et al. publications and the submission of a Rule 132 Declaration of the inventor, William J. Schmidt. An Advisory Action issued on August 30, 2001 refusing to enter the Schmidt Declaration. Applicant thereafter filed a continuation application (CPA) on September 19, 2001 including the previously unentered Declaration of William J. Schmidt which was subsequently entered and is of record herein.

On October 2, 2001, a non-final Office Action issued rejecting all pending claims (claims 1-5, 7, 8, 10-27, 44 and 46-70) solely on prior art grounds as anticipated or obvious by Applicant's prior patent, Schmidt et al. (U.S. Patent No. 5,288,408). The claims were not rejected based on the Fain et al., Dutre et al. or Chakravorty et al. publications. An Amendment was filed on January 14, 2002 canceling all pending claims and adding new claims 71-83 which are the claims currently pending in this Appeal. A final Office Action issued on May 21, 2002 rejecting the claims on technical grounds (35 U.S.C. Section 112) and on prior art grounds based solely on the Schmidt et al. reference. A response was filed on August 20, 2002 along with a timely filed Notice of Appeal.

In response to the filing of the Appeal Brief on December 23, 2002, the Patent Examiner issued an Office Action on March 13, 2003. The Office Action restated all prior rejections set forth in the final Office Action of May 21, 2002 with an additional

ARK:jsg060804/6711002CIP-3.BOA

rejection under 35 U.S.C. Section 103 based on the combination of Schmidt et al. and Dutre et al., the latter reference being cited for the first time since the final Office Action of January 31, 2001. A response was filed on May 14, 2003.

A final Office Action issued on August 13, 2003 repeating the rejection in the previous Office Action. Applicant filed on November 13, 2003 a request to reinstate the Appeal which was rejected in a paper dated May 12, 2004 on the ground that Applicant had not formally addressed the rejection based on Schmidt et al. and Dutre et al.

On June 12, 2004, Applicant resubmitted the Brief on Appeal updating Section 4 (Background of Application) and formally traversing the prior art rejection based on Schmidt et al. and Dutre et al.

(5) Summary Of Invention:

The present invention is generally directed to a method of treating a waste material containing gelatin. Typically, the waste gelatin material will be obtained as a by-product from the manufacture of soft gel capsules. In accordance with the present method, the waste material is combined with a solvent for the gelatin (e.g. water) under conditions sufficient to form a gelatin-containing liquid. The starting waste gelatin material is required to contain at least one component which cannot effectively be separated from the gelatin-containing liquid into a non-solvent based layer as discussed below.

Thus, the waste material is required to have at least one component which remains with a solvent based layer because it cannot be separated into a non-solvent based layer.

The second step of the inventive method is the step that forms the solvent based layer and the non-solvent based layer. What is important to the claimed invention is that the first component remains with the solvent based layer and it is the solvent based layer which is thereafter treated.

The third step of the method concerns the treatment of the solvent based layer which contains the first component. This treatment step removes the first component thereby forming another liquid which contains gelatin having a higher purity than the first liquid because the first component has been removed therefrom.

Step (a) of the present method in which the waste material is combined with a solvent for the gelatin is described in the application at page 6, lines 3-4. Support for the waste material containing at least one first component which cannot be effectively separated from the first liquid into a non-solvent based layer is described in the specification at page 9, lines 3-7 wherein the definition of the solvent based layer states that the components therein dissolve in the solvent and therefore may be separated from the non-solvent based layer which includes components that do not dissolve in the solvent.

Step (b) of the present method in which the first liquid is separated into a solvent based layer and a non-solvent based layer is described at page 9, lines 15-20.

Step (c) of the method requires the removal of the first component from the solvent based layer. In this regard, it should be noted that at page 9, line 11 of the application it is stated that the upper non-aqueous layer (non-solvent based layer) is either discarded or recycled. The present application is concerned with the components which are contained within the solvent based layer such as particulates and/or oily type materials as described on page 13, lines 11-13. These components must be removed from the solvent based layer in order to purify the gelatin which is contained therein. Specific treatment methods are set forth beginning at page 13, line 14.

Claim 72 requires that the first component is selected from oily type materials, particulates and combinations thereof as described in the specification at page 13, lines 11-13. Claim 73 identifies specific processes that are employed as the treating step to treat the solvent based layer including liquid:liquid centrifugation, submicron/microfiltration, coalescers, and combinations thereof as disclosed on page 13, lines 14-19. The employment of a tangential flow filter as required in claim 74 is disclosed on page 15, lines 13-17.

Claim 75 covers a preferred temperature range of from about 30 to 70°C which is disclosed in the specification at page 16, line 3 as well as on page 14, lines 14-16.

Diluting the solvent based layer to a dilution volume of up to 5 volumes of the solvent as required by claim 76 is disclosed at page 14, lines 14-16, as well as, page 16, lines 14-16.

Claim 77 provides that Step (c), after removing the oily type materials and particulates from the solvent based layer to form a filtrate, requires recycling of the filtrate. This aspect of the claimed invention is disclosed in the specification at page 18, lines 4-6. The filtrate may be treated as required in claim 78 to remove at least some of the solvent as disclosed at page 18, lines 5 and 6. Claim 79 requires that the filtrate be subjected to a process selected from the group consisting of vacuum distillation, diafiltration, and short path distillation as disclosed on page 18, lines 8-12.

The employment of a softening agent such as glycerin (see claims 80 and 81) is disclosed at page 6, lines 16-18 as well as page 7, lines 6-8.

The employment of ultrafiltration to remove the softening agent is described in original claim 26. Finally, claim 83 identifies water as a preferred solvent which is disclosed throughout the specification as, for example, at page 8, lines 4-6 as well as, for example, at page 13, line 8, and page 14, line 11.

(6) Issues:

a) Whether claims 71-83 meet the requirements of 35 U.S.C. Section 112 first paragraph:

i. whether the language in claim 71 “said waste material containing at least one first component which cannot effectively be separated from the first liquid into a non-solvent based layer” is described in the specification;

ii. whether the language in claim 72 “The method of claim 1 wherein the first component is selected from oily type materials, particulates and combinations thereof having an affinity for the solvent” is supported in the specification as filed;

iii. whether claim 72 covers subject matter which the specification fails to teach those skilled in the art and particularly how to differentiate between “particulate and/or oily type” contaminants of a trace nature from those having an affinity for the solvent based layer.

b) whether claims 71-83 meet the requirements of 35 U.S.C. Section 112, second paragraph:

i. whether claim 71 and particularly the language “said waste material containing at least one first component which cannot effectively be separated from the

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first liquid into a non-solvent based layer” is indefinite for failure to particularly point out and distinctly claim the subject matter of the invention;

ii. whether claims 71-83 fail to correspond in scope with what Applicant regards as the invention because the claims fail to mention anything about the method being “in situ”,

c) whether claims 71-83 are anticipated by Schmidt et al. U.S. Patent No. 5,288,408 under 35 U.S.C. § 102;

d) whether claims 71-83 are rendered obvious by Schmidt et al. U.S. Patent No. 5,288,408 under 35 U.S.C. § 103; and

e) whether claims 74 and 82 are rendered obvious by Schmidt et al. (U.S. Patent No. 5,288,408) in view of Dutre et al. under 35 U.S.C. Section 103.

(7) Grouping Of Claims:

The rejected claims 71-83 stand or fall together.

(8) Argument:

The present invention is directed to a method of treating a waste material containing gelatin with the purpose of eliminating or at least substantially reducing the impurities therein so that a purified gelatin product may be recycled back to the

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operation which employs the gelatin starting material (e.g. soft gel capsule manufacture).

The waste material is combined with a solvent for the gelatin to form a liquid which contains the gelatin. It is important to note that the method requires that the waste material contain at least one first component which cannot effectively be separated from the first liquid into a non-solvent based layer. Accordingly, Step (a) of the present invention identifies a particular type of waste material containing gelatin. The waste material contains at least one first component which cannot effectively be separated from the liquid formed by combining the waste material and a solvent for the gelatin into a non-solvent based layer.

The method then requires separating the liquid into two layers. One of the layers is a solvent based layer which contains the gelatin and the first component. The second layer is a non-solvent based layer. As will be discussed in detail below, the first component is present in the solvent based layer because it has an affinity for the solvent (e.g. is dissolved therein) and does not have an affinity for the non-solvent based layer.

In accordance with a critical aspect of the present invention, Step (c) concerns treatment of only the solvent based layer. The purpose of this treatment step is to remove the first component from the solvent based layer. By doing so, the resulting liquid [i.e. the second liquid as referred to in Step (c)] contains a higher purity of gelatin because it is at least substantially devoid of the first component.

Issue (a)(i):

The language in claim 71 namely “said waste material containing at least one first component which can not effectively be separated from the first liquid into a non-solvent based layer” is fully described in the application as filed.

Claim 71 of the present application requires the presence of at least one first component. The first component ends up in the solvent based layer as opposed to the non-solvent based layer, when the two layers are separated in accordance with Step (b) of the method. The separation step is described at page 9, line 15 to page 10, line 9. Separation of the two layers can be accomplished, for example, by letting the first liquid stand allowing for gradual separation over the course of 1 to 3 hours. Differences between the two layers can be facilitated by a sight glass or an oil skimmer may be employed to remove the non-solvent layer (e.g. non-aqueous layer) while the solvent based layer (e.g. the aqueous layer) is further processed (page 10, lines 6-9).

One of ordinary skill in the art would therefore appreciate that the purpose of the separation step is to isolate the solvent based layer for further treatment in accordance with Step (c). During the separation procedure the “at least one first component” will end up in the solvent based layer as opposed to the non-solvent based layer. An alternative way of expressing this feature of the invention is to indicate that the “at least one first component” does not end up in the non-solvent based layer. This language was incorporated into claim 71 to emphasize the material distinctions between the claimed invention and the Schmidt et al. prior art reference which concerned treatment

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of the non-solvent based layer. Not only would one of ordinary skill in the art understand the purpose of the separation step, but would also appreciate that the contaminants meeting the definition of "at least one first component" will substantially end up in the solvent based layer. It will also be appreciated that depending on the separation technique used (e.g. an oil skimmer), the first component may not be entirely separated into the solvent based layer. For example, a very small amount of the first component might be trapped in the non-solvent based layer. Accordingly, Applicant chose the words "can not effectively be separated from the first liquid" to limit the first component to those in which a substantial portion ends up in the solvent based layer although, it is possible that a very small amount could end up in the non-solvent based layer depending on the effectiveness of the particular separation technique chosen. Quite clearly, the present invention is concerned with the treatment of the solvent based layer and specifically removal of the first components contained therein.

It is respectfully submitted that Applicant has complied with the written description requirement. The test for determining compliance with the written description is whether the disclosure reasonably conveys to one of ordinary skill in the art that in the inventor had possession of the invention set forth in the claims. In re Kaslow 217 U.S.P.Q.1089 (Fed Cir. 1983). The invention claimed does not have to be described ipsis verbis. It is sufficient to meet the written description requirement that the description is sufficiently clear that the person of ordinary skill in the art will recognize that Applicant made the invention having those limitations. Martin v. Mayer 3 U.S.P.Q. 2d 1333 (Fed. Cir. 1987).

It is respectfully submitted that Applicant made the invention as recited in Step (a) because there is full support in the application for employing a waste material containing a first component which principally ends up in the solvent based layer and then treating the solvent based layer to remove the first component.

Issue (a)(ii):

The language in claim 72 namely “the first component is selected from oily type material particulates and combinations thereof having an affinity for the solvent” is fully described in the application.

Page 13, lines 11-13 of the specification states that the separated solvent based layer (e.g. aqueous layer) contains particulates and/or oily type materials which are specific examples of the first component contaminants of interest in the present invention and referred to in the present claims. These materials end up in the solvent based layer such as by being dissolved therein.

The phrase “having an affinity for the solvent” as used in claim 72 would be understood by one of ordinary skill in the art to mean that the particular first components referred to in the claim end up in the solvent based layer rather than the non-solvent based layer because such components preferentially associate with the solvent such as by becoming dissolved therein. Because this phrase essentially restates what is set forth in claim 71 and because the phrase would be understood by those skilled in the art, claim 72 meets the written description requirement of 35 U.S.C. § 112.

Issue (a)(iii)

Claim 72 covers subject matter which is fully enabled under 35 U.S.C. § 112.

Claim 72 has been rejected on the ground that the Applicant fails to teach one skilled in the art how to differentiate the particulate and/or oily type materials (i.e. specific examples of first components) that end up in the solvent based layer from those that end up in the non-solvent based layer.

This ground of rejection is without foundation and clearly does not take into account what is disclosed in the specification and what is within the routine skill of the art. As previously stated, the starting waste material of the present invention includes gelatin and at least one first component. The first component must end up in the solvent based layer because it is the solvent based layer that is being treated in accordance with method Step (c). The solvent based layer will contain first components which have an affinity for the solvent based layer (otherwise they would end up in the non-solvent based layer) and are therefore not effectively separated into the non-solvent based layer. As also previously stated, one of ordinary skill in the art would understand that the non-solvent based layer may also contain contaminants. These will include, logically, those contaminants which do not have an affinity for the solvent (e.g. are insoluble in the solvent) and perhaps very small amounts of the first components owing to the limitation of the specific separation technique employed in Step (b) of the method (i.e. no separation technique is 100% effective).

What is important is that Applicant's invention is directed to the treatment of the solvent based layer, not to the treatment of the non-solvent based layer which is the subject of the invention described in the sole prior art reference cited against the present claims.

Thus, the present application teaches one of ordinary skill in the art the specific requirements for a contaminant to be judged a first component (i.e. must have an affinity for the solvent so that the contaminant ends up in the solvent based layer and does not "effectively" end up in the non-solvent based layer except for minor amounts which may appear therein because of limitations on the separation technique). Furthermore, the first component is one that can be removed from the solvent based layer by treatment Step (c).

Issue (b)(i):

Claim 71 is not indefinite for failure to particularly point out and distinctly claim the invention because the claim does enable one skilled in the art to select a suitable starting waste material.

Step (a) of claim 71 has been discussed in connection with issue (a)(i). Briefly the first component is one which ends up in the solvent based layer when the two layers are separated. One of ordinary skill in the art through the use of no more than a basic chemical text could readily predict with the requisite degree of certainty which contaminants end up in the solvent based layer. If the contaminant ends up in the solvent based layer (e.g. dissolved therein) it necessarily follows that such contaminants

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can not be "effectively separated into the non-solvent based layer". Since one of ordinary skill in the art can identify which contaminants are present in the waste gelatin material, the skilled artisan can likewise determine without any undue experimentation which layer the respective contaminants will enter and then treat the solvent based layer containing at least one first component as required by the present claims.

The Examiner refers to page 13, lines 11-13 of the specification. It is asserted that the word "If" as used therein renders the claims indefinite. In particular, the specification states:

"If the separated aqueous layer contains particulates and/or oily types of materials, the aqueous layer may then be treated to remove residual oils and/or particulates by means of hot filtration processes as more fully described below."

The Examiner then states "Given that there may not be any of the contaminants of interest in the present invention, . . . The meaning of the claims is not clear when the contaminants are not present."

The Examiner's position is untenable. The claims require the presence of a first component as part of the waste material. If a first component is not present, the treatment of such waste material is clearly outside the scope of the claims. Page 13, lines 11-13 merely clarifies the scope of the claimed method (i.e. treatment of a specific

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type of waste gelatin material) and in no way suggests that the claimed invention encompasses waste material which does not contain at least one first component. The position taken by the Examiner is contrary to the overall description of the invention in the specification and the claims which are the subject of this appeal.

Issue (b)(ii)

Failure to mention "in situ" does not expand the claims beyond the scope of the disclosed invention.

This ground of rejection is premised on a distorted and clearly unsubstantiated reading of the prior art Schmidt et al. reference (U.S. Patent No. 5,288,408) as will be fully discussed in the issue section pertaining to the prior art under 35 U.S.C. Sections 102 and 103. Suffice to say that the differences between the claimed invention and the process disclosed in Schmidt et al. are sufficiently material that the claimed invention is patentable over the Schmidt et al. reference without mentioning the words "in situ".

Issues (c) and (d)

The claims of the present application are not anticipated or rendered obvious by Schmidt et al. U.S. Patent No. 5,288,408.

As previously indicated, the present invention is directed to a process by which a waste material containing gelatin is further treated to remove contaminants (i.e. first components) from the waste material which have an affinity for the solvent. The waste material is combined with a solvent (e.g. water) to form a first liquid. The solvent dissolves the waste gelatin material to form a solution of gelatin and glycerin (i.e.

solvent based layer which may contain contaminants identified herein as “first components” such as oily type materials and particulates) within the remaining oily layer (see page 8, line 19 to page 9, line 7). The non-solvent based layer is separated from the solvent based layer. At this juncture, the method disclosed in Schmidt et al. U.S. Patent No. 5,288,408 and the present application are similar except that Schmidt et al. does not require a waste gelatin material which must have a first component as defined herein.

As previously indicated, the separation of the non-solvent based layer from the solvent based layer is not a 100% exact science. Using skimmers and sight glasses will provide for a substantial separation, but typically not a complete separation of the solvent based layer from the non-solvent based layer. The process described in Schmidt et al. U.S. Patent No. 5,288,408 as more fully discussed below, is concerned with removing the remaining trace amounts of the non-solvent based contaminants from the non-solvent based layer but does not teach or suggest any process for removing contaminants which have an affinity for the solvent based layer.

To the contrary, the present invention is concerned with removing contaminants of the waste stream (i.e. first components) which have an affinity for the solvent based layer.

In this regard, the Schmidt et al. U.S. Patent No. 5,288,408 (hereinafter “the ‘408 Patent”) is clear that the contaminants being removed are those having an affinity for the “non-solvent based layer” and the only treatment performed on the solvent

based layer is the removal of remaining traces of those contaminants which have an affinity for the non-solvent based layer. More specifically, the '408 Patent discloses beginning at column 4, line 1 the separation of the lower aqueous phase (solvent based layer) from the upper oil phase (non-solvent based layer) by a sight glass. The '408 Patent further states that the upper phase (non-solvent based layer) may contain the lubricating or coating oils, active ingredients, colorants and preservatives which may themselves be subject to certain novel recycling techniques. As indicated in the sentence beginning at page 4, line 16 the subject invention (i.e. the invention of the '408 Patent) provides a method for more efficient recovery of active ingredients (referred to above as contained within the upper non-solvent based layer).

Insofar as the lower phase (solvent based layer) is concerned, column 4, line 22 of the '408 Patent indicates that it is filtered to remove "any remaining traces of oil or other contaminants". The only oil or other contaminants referred to in the '408 Patent specification are those that reside in the non-solvent layer. Thus, the '408 Patent uses certain types of filter equipment to remove the last remaining traces of contaminants that spilled over from the separation process of Step (b) so that the filtrate containing gelatin and glycerin is not contaminated with these non-solvent based contaminants. This is the only reasonable interpretation that can be applied to the clear teaching of the specification of the '408 Patent. There is no teaching or suggestion of how to remove first components from the solvent based layer.

The '408 Patent at column 4, lines 22-31, states that the type of filters that may be used to remove such contaminants include coated or uncoated plate filters, nutche

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filters or cartridge filters each of which was well known to those skilled in the art at time of the Schmidt et al. invention. The type of filters (e.g. cartridge filters) described in the '408 Patent are generally comprised of filters which allow liquid to flow therethrough. They do not permit passage of particulate materials of the type expected when trace amounts of contaminants which have an affinity for the solvent based layer are present in the non-solvent based layer.

However, such filters are not effective in removing contaminants which have an affinity for the solvent based layer. Materially different systems must be used as described in detail beginning at page 13, line 14 of the present application and covered specifically by claims 73 and 74. This was the subject of the comparative testing summarized in the Declaration of the inventor, William J. Schmidt of record in the present application.

The Declaration of William J. Schmidt (hereinafter the "Schmidt Declaration") attests to actual experiments including scale up experiments that were performed during the course of the past three years at commercial facilities to improve upon the technology described in the '408 Patent.

The Declarant, William J. Schmidt chronicles the efforts made to treat a waste stream containing oils with hydrophilic groups, aromatic oils and suspended particles (e.g. titanium dioxide). In this regard, various tests were performed by reputable filter companies and capsule manufacturers in an effort to commercialize the '408 Patent technology. The Schmidt Declaration focuses on test procedures performed on waste

gelatin streams that could not be effectively treated by the '408 Patent technology. In this regard, Paragraph 7 of the Schmidt Declaration indicates that the process disclosed in the '408 Patent does not perform on a commercially acceptable scale when the waste gelatin stream contains one or more specific contaminants including oils with hydrophilic functioning groups, such as vitamin E acetate, aromatic oils such as fish oil and garlic oil, and suspended or particulate colorants such as titanium dioxide (i.e. first components having an affinity for the solvent based layer).

Since commercial success of the present technology would require the removal of such materials, efforts were made to improve upon the technology of the '408 Patent developing specific treatments that could effectively remove contaminants of interest herein and particularly those having an affinity for the solvent based layer and which are not effectively separated into the non-solvent based layer.

On or about August, 1998, tests were performed at General Nutrition Products in which a waste gelatin stream containing gelatin, glycerin and vitamin E acetate (an oil with a hydrophilic functional group; a contaminant having an affinity for the solvent based layer) was tested in accordance with the procedure set forth in Paragraph 10 of the Schmidt Declaration. The solvent based layer was separated from the non-solvent based layer. The solvent based layer was then treated in accordance with the '408 Patent using a 10 micron polypropylene cartridge filter of the type specifically referred to in the '408 Patent at column 4, line 27. The resulting filtrate was observed to have a

ARK:jsg060804/6711002CIP-3.BOA

milky white and therefore unacceptable appearance due to the presence of residual emulsified oil (oil with hydrophilic functional groups) and was therefore unsuitable for commercial scale recycling of gelatin.

In May, 2000 at another facility, a waste stream very similar to the waste stream described above was treated with the same cartridge filter taught by the '408 Patent but then was treated in accordance with the present invention using a 0.65 micron tangential flow microfilter (microfiltration), particularly suited to remove first components having an affinity for the solvent based layer. The gelatin recovered from this example was observed to have a clear, amber appearance typically associated with previous unprocessed gelatin. It was the treatment specifically claimed in the present application which achieved the clear recycled gelatin where the '408 Patent technology did not succeed. Nothing in the '408 Patent teaches or suggests this surprising and unobvious result.

When the resulting recyclable gelatin product was obtained, it was tested for stability and other characteristics which are a necessary part of using a recycled product as indicated in Paragraph 14 of the Schmidt Declaration. The results showed that the recyclable gelatin obtained in accordance with the present invention was of similar quality to virgin gelatin.

As indicated in Paragraph 16 of the Schmidt Declaration, an effort was made to modify the process of the '408 Patent to remove residual emulsified oils (i.e. a first

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component) by using a smaller pore cartridge filter. One micron and 0.3 micron cartridge filters were tested. However, the one micron filter was too large to remove the residual oils while the 0.3 micron cartridge filter resulted in an unacceptable throughput.

In a still further effort to modify the process described in the '408 Patent, a 0.5 micron cartridge filter was used at a reduced back pressure. As indicated in Paragraph 18 of the Schmidt Declaration, tests were performed on a waste stream containing gelatin, glycerin and fish oil (a contaminant having an affinity for the solvent based layer). One sample run employed a one micron cartridge filter according to the teaching of the '408 Patent. The resulting permeate had a distinct "fishy smell" and therefore did not remove a sufficient quantity of the fish oil. When the process was carried out in accordance with the present invention incorporating a 0.65 micron tangential flow microfilter (i.e. microfiltration), the resulting permeate was odor free indicating that essentially all of the fish oil had been removed, a surprising and unobvious result of the present application. Indeed, these test results clearly show that modifying the pore size of the '408 Patent technology was not successful in removing the above-mentioned contaminants.

As indicated in Paragraph 19 of the Declaration, similar results have been obtained when the waste stream contains another first component (i.e. submicron particle size titanium dioxide) which is a colorant typically suspended in the waste gelatin. It should be noted that the preferred procedure for removing such particles is centrifugation as specifically described and claimed in the present application.

As previously indicated, the '408 Patent teaches the use of cartridge filters and equivalent devices. There is no indication in the '408 Patent of the nature of the particular contaminants, if any, contained in the lower phase (solvent based layer) and the effectiveness of removing the same through the use of the various specific filters set forth in column 4. The '408 Patent describes the treatment of waste gelatin streams to remove contaminants have an affinity for the non-solvent layer. To the extent that trace amounts of contaminants having an affinity for the non-solvent based layer spill over to the solvent based layer, cartridge type filters are suitable to remove these trace contaminants. However, the present invention provides that if certain contaminants (first contaminants) are present (e.g. oils having hydrophilic groups, aromatic oils, and suspended particles) then the technology of the present application must be employed to remove these contaminants from the solvent based layer to get an effective recyclable stream of gelatin. The Declaration of William J. Schmidt clearly shows that this is the case. Accordingly, the present invention is patentable over what is fairly disclosed in the '408 Patent.

The Schmidt Declaration also shows that leading manufacturers of soft gelatin capsules were introduced to and aware of the '408 Patent technology but did not recognize how to remove first contaminants (e.g. the oily contaminants and suspended particles) from the waste stream. Had they recognized how to accomplish this task in light of the '408 Patent, they would have done so and would not be engaged in license negotiations for the present technology.

Issue (e)

The claims of the present application are not rendered obvious by Schmidt et al. U.S. Patent No. 5,288,408 in view of Dutre et al.

Dutre et al. is stated to disclose the use of tangential flow tubular membrane ultrafiltration to concentrate gelatin and the benefits associated with ultrafiltration concentration including lower costs and higher purity.

Dutre et al. describes the ultrafiltration of a gelatin liquor containing sodium chloride. In particular, the reference concerns diafiltration (i.e. ultrafiltration in a dilution mode) as applies to a gelatin/sodium chloride containing solution. When diafiltration with a permeate-forced solvent stream is used instead of classical diafiltration, the efficiency of the process is improved.

However, ultrafiltration cannot be employed in step (c) of the claimed process to remove the first component from the solvent based layer to form a second liquid containing gelatin having a higher purity than the first liquid being at least substantially devoid of the first component.

The Ultrafiltration Handbook authored by Munir Cheryn, of record in the present application, describes five major membrane filtration processes which include reverse osmosis, microfiltration, ultrafiltration, dialysis and electrodialysis which cover a wide

range of particle sizes. Depending on the membrane construction, ultrafiltration can also be referred to as “microporous ultrafiltration”.

Page 2 of Cheryan states that microfiltration processes are designed to retain particles in the “micron” range, that is, suspended particles in the range of 0.10 μm to about 10 μm . Page 4 states that microfiltration is also a method for essentially separating suspended particles from dissolved substances in a feed stream, provided the particles meet the requirements of microfiltration membranes. Microfiltration as applied in the present application as one of the techniques to carry out step (c) is employed to remove first components which may be in the form of particles from the dissolved gelatin, as for example, emulsified oil and residual oil droplets in the “micron” range as described above. Microfiltration is a physical separation of dissolved and undissolved components of a process stream based on particle size. Ultrafiltration techniques such as disclosed in Dutre et al. cannot remove the first component as described in the present application including oil droplets or emulsified oil from dissolved gelatin.

Ultrafiltration (or microporous microfiltration) as described in Dutre et al. is a filtration technique designed to preferentially separate different kinds of fluids or ions. Ultrafiltration is most commonly used to separate a solution having dissolved components to remove undesirable dissolved components. Microporous ultrafiltration is not capable of removing residual oil droplets or emulsified oils. In brief, ultrafiltration is concerned with solutions and removing different components within a solution while

microfiltration separates suspended particles, including suspended oil particles, from a solution.

The substitution of an ultrafiltration technique of the secondary reference in the waste gelatin recovery process of Schmidt et al. does not result in a method of treating a waste gelatin material that is capable of removing residual oils and/or particulates from the gelatin solution. If residual oils and particulates cannot be removed from the waste gelatin stream, the process has no practical value. Ultrafiltration cannot remove these materials because it is a technique solely directed to removing dissolved components from a solution. To the contrary, the stream which is treated in accordance with the present invention is a solvent based layer containing at least one first component which cannot effectively be separated from the first liquid into a non-solvent based layer.

Ultrafiltration can be used in the claimed process as set forth in claim 82 to dewater the usable waste gelatin product (i.e. to separate water from an aqueous solution of gelatin) to raise the concentration of gelatin in the waste stream. However, at this step of the process, the first components must have already been removed.

It is therefore submitted that the claims appealed from in the present application are not properly rejected over the references of record under 35 U.S.C. Section 102,


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103 and 112 and the Board of Appeals is respectfully requested to grant this Appeal and reverse the Examiner's rejections.

ADDRESS ALL CORRESPONDENCE TO:

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Respectfully submitted,


Allen R. Kipnes, Esq.
Registration No. 28,433
Attorney for Applicant

APPENDIX

(9) Claims of Record:

71. A method of treating a waste material containing gelatin comprising:

(a) combining the waste material and a solvent for the gelatin under conditions sufficient to form a first liquid containing gelatin, said waste material containing at least one first component which can not effectively be separated from the first liquid into a non-solvent based layer;

(b) separating the first liquid into a solvent based layer containing the gelatin and said at least one first component and a non-solvent based layer; and

(c) treating the solvent based layer with a process which removes the first component from the solvent based layer to form a second liquid containing gelatin having a higher purity than the first liquid being at least substantially devoid of the first component.

72. The method of claim 1 wherein the first component is selected from oily type materials, particulates and combinations thereof having an affinity for the solvent.

73. The method of claim 71 wherein step (c) comprises treating the solvent based layer with a process selected from the group consisting of liquid:liquid centrifugation, sub micro/microfiltration, coalescers, and combinations thereof.

74. The method of 73 wherein step (c) comprises treating the solvent based layer with a tangential flow filter.

75. The method of claim 71 wherein step (c) is carried out at a temperature of from about 30 to 70°C.

76. The method of claim 75 wherein the solvent based layer is diluted at a dilution volume of up to 5 volumes of said solvent.

77. The method of claim 71 wherein the waste material contains oily type materials and particulates, step (c) comprising removing the oily type materials and particulates from the solvent based layer to form a filtrate and recycling the filtrate.

78. The method of claim 71 wherein the waste material contains oily type materials and particulates, step (c) comprising removing the oily type materials and particulates from the solvent based layer to form a filtrate and treating the filtrate to remove at least some of the solvent.

79. The method of claim 78 wherein the step of treating the filtrate comprises subjecting the filtrate to a process selected from the group consisting of vacuum distillation, diafiltration and short path distillation.

80. The method of claim 71 wherein the waste material contains a softening agent, said softening agent being separated into the second liquid.

81. The method of claim 80 wherein the softening agent is glycerin.
82. The method of claim 80 further comprising subjecting the second liquid to ultrafiltration to remove the softening agent therefrom.
83. The method of claim 71 wherein the solvent is water.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant William J. Schmidt
Serial No. 09/385,405
Filed : August 30, 1999
For : METHOD FOR THE PURIFICATION AND
RECOVERY OF WASTE GELATIN
Examiner : R. Popovics
Art Unit : 1723
Attorney Docket No. : 671.1.002 CIP-3



I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS
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20231

ON August 10, 2001

NAME Jill S. Garretson

SIGNATURE *Jill S. Garretson*

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

August 10, 2001

DECLARATION

Dear Sir:

I, William J. Schmidt, declare and say as follows:

1. I am the sole inventor of the subject matter of the present application.

5 Furthermore, I am fully familiar with Schmidt, U.S. Patent No. 5,288,408 (hereinafter
"the '408 Patent"), cited as a reference against the claims of the pending application,
as I am one of the inventors of the '408 Patent.

2. I submit this Declaration and supporting documentation in support of the patentability of the claims of the pending application.

3. The '408 Patent discloses process technology for recovering gelatin and glycerin from a waste stream containing the same. The waste stream is dissolved in a solvent (e.g. deionized water) at a temperature of from 60 to 70°C and then diluted with deionized water to form an aqueous solution of gelatin and glycerin dispersed within the remaining oil and residual active-ingredient components ('408 Patent, column 3, lines 40-56).

4. The lower aqueous phase containing gelatin and glycerin is separated from the upper phase which typically contains lubricating or coating oils (e.g. mineral oil), active ingredients, coloring agents and preservatives (column 4, lines 9-13).

5. The lower phase (i.e. the aqueous phase) is hot filtered by the use of a plate filter, coated plate filter nutche filters or cartridge filters to remove any remaining trails of oil or other contaminants (column 4, lines 22-28) to form a filtrate.

6. The filtrate may then be concentrated by removing a portion of the water through the use of a vacuum distillation process (column 4, lines 32-63).

7. From the time of filing (October 26, 1992) of the patent application which led to the '408 Patent, I have personally observed that the process disclosed in the '408 Patent does not perform on a commercially acceptable scale when one or more of the

specific contaminants including oils with hydrophilic functioning groups (e.g. vitamin E acetate), aromatic oils such as fish oil and garlic oil, and suspended or particulate colorants such as titanium dioxide are present in the waste stream.

8. The present invention sought to improve upon the technology disclosed
5 in the '408 Patent and was developed in response to commercial market criteria and the needs expressed by principal users of gelatin for the manufacture of soft gelatin capsules. In this regard, it was observed that a significant portion of waste gelatin produced commercially, especially in the soft gelatin capsule market contained material amounts of oils with hydrophilic functional groups, aromatic oils, and/or suspended
10 particles.

9. The following tests are submitted to demonstrate the advantages of the present invention over what is fairly disclosed in the '408 Patent and were performed, coordinated and/or observed by me.

10. On or about December, 1998, the following test was performed at General
15 Nutrition Products in Greenville, South Carolina. The test procedures and results are shown in Exhibit A herein. A waste gelatin stream containing gelatin, glycerin and vitamin E acetate (an oil with hydrophilic function groups) at a flow rate of 200 liters per minute at 50°C was treated in accordance with the '408 Patent by subjecting the aqueous phase, after separation from the non-aqueous phase, to treatment with a
20 10-μ polypropylene cartridge filter until a total of 140 kilograms of waste gelatin was treated. The resulting filtrate was then concentrated using ultra-filtration to obtain a

concentrated sample for analysis. Ultra-filtration was used for concentration because it was considered a more effective process for concentrating (i.e. dewatering) the filtrate than vacuum distillation as specifically disclosed in the '408 Patent.

11. The filtrate produced in accordance with paragraph 10 herein was
5 observed to have a milky white appearance due to the presence of an unacceptable amount of residual emulsified oil. The resulting filtrate was deemed unsuitable for commercial scale recycling of gelatin.

12. On or about May, 2000, the following test was performed at Intergel,
Division of IVC Industries in Irvington, New Jersey. The test procedures and results are
10 shown in Exhibit B herein. A waste gelatin stream containing gelatin, glycerin and vitamin E acetate (an oil with hydrophilic function groups) at a flow rate of 200 liters per minute at 50°C was treated by subjecting the aqueous phase, after separation from the non-aqueous phase, to treatment with a 10- μ , polypropylene cartridge filter to produce a first filtrate. The first filtrate was then treated with a 0.65- μ tangential flow microfilter
15 until a total of 145 kilograms of waste gelatin was treated. The resulting filtrate was then concentrated using ultra-filtration to obtain a concentrated sample for analysis.

13. The filtrate produced in accordance with Paragraph 12 herein was
observed to have a clear, amber appearance typically associated with previous
unprocessed gelatin. The microfiltration step employed in accordance with the present
20 invention surprisingly eliminated residual emulsified oils to the extent that they were essentially undetectable in the resulting filtrate.

14. Soft gelatin capsules were successfully manufactured from the recovered gelatin product produced in accordance with Paragraph 12. In addition, a 3 month accelerated stability test was performed on the resulting capsules as compared with a control containing no recycled gelatin. The results showed no change in physical appearance compared to the control, no change in fill assay compared to the control, no change in microbiological parameters compared to the control, no change in dissolution profile compared to the control, a capsule strength and a seal strength equal to or exceeding the control, and adhesive properties equivalent to or better than the control (See Exhibit B).

15. On or about April, 1999 a series of tests similar to that described in Paragraphs 12-14 were performed at Pall Filtron Corporation, witnessed by representatives of General Nutrition Products and Intergel, with the exception that a 0.45- μ tangential flow microfilter was used to treat the waste gelatin instead of a 0.65- μ tangential flow microfilter. The results were very similar to that described in Paragraphs 12-14 herein, i.e the waste gelatin had a clear, amber appearance with essentially no detectable emulsified oils.

16. In October, 2000, large scale trials were performed at Nutricia Manufacturing USA, Inc. on behalf of Millipore Corporation (a licensee to Applicant herein) on a waste gelatin stream similar to that described in Paragraphs 10-14 to determine if a smaller pore cartridge filter in accordance with the '408 Patent could be effectively used to remove the residual emulsified oils. The test procedures and results are shown in Exhibit C herein. In this regard, a 1- μ and 0.3- μ cartridge filter were

tested. The 1- μ cartridge filter did not remove the residual oils. The 0.3- μ cartridge filter resulted in a reduced a unacceptable throughput and eventual oil breakthrough. Millipore's conclusion regarding this test was:

5 "Due to low filtrate throughput and early
breakthrough, the number of cartridges required for this
application is very large and thus, the process becomes
unrealistic."

10 17. In or about February, 2001, laboratory scale tests (900 ml batch size)
were performed similar to the tests described in Paragraph 16 using a 0.5- μ cartridge
filter at a reduced back pressure (i.e. 10 psig instead of 15 psig). The results showed
very low throughput and oil breakthrough when the back pressure was increased. A 1- μ
cartridge filter was used successfully on a laboratory scale at 10 psig but resulted in oil
breakthrough when the batch size was increased from 900 ml to 120 l. It was thus
clearly demonstrated by the test set forth in paragraphs 16 and 17, that cartridge
15 filtration, as described in the '408 Patent, even with a smaller pore size, does not
achieve the removal of contaminants achieved by the use of tangential flow
microfiltration as taught by the present invention. I consider this discovery to be
surprising and unobvious from the '408 Patent disclosure.

20 18. In or about August, 2000 processes similar to that described in
Paragraphs 10 and 12 respectively were conducted (See Exhibit D herein) on a waste
gelatin stream containing gelatin, glycerin, and fish oil. In particular, a waste gelatin

stream (400 kg total batch) at a flow rate of 200 liters per minute at 50°C was treated with a 1- μ cartridge filter which resulted in a permeate having a distinct "fishy smell". When the process was carried out under the same conditions using a 1- μ cartridge filter and a 0.65- μ tangential flow microfilter, the permeate was odor free indicating that essentially all of the fish oil had been removed. The test procedures and successful results obtained in accordance with the present invention are shown in Exhibit D herein.

19. A waste stream containing suspended colorants such as titanium dioxide having an average particle size of 0.3- μ would require a cartridge filter having a pore size of about 0.1- μ . However, as discussed in paragraphs 16 and 17 herein, such small pore sizes would reduce the throughput of the waste stream to an extent that the process would be unacceptable on a commercial scale. Coated plate filters of the type described in the '408 Patent which typically have a pore size of 1- μ would allow the suspended particles to pass therethrough. Rosenmund and/or Nutche type filters are much too expensive to be practical for the commercial operation of treating waste streams containing suspended particles.

20. In accordance with the present invention, centrifugation which does not rely on pore size, has been successful in removing suspended particles from a waste gelatin stream containing the same.

21. I am aware that the Office Action states that the claimed invention is obvious in light of the '408 Patent. In addition to the comparative data presented herein, it is my view that the capsule manufacturing industry did not consider it obvious

to proceed from the technology disclosed in the '408 Patent to the technology claimed in the present application because the differences were not obvious. The industry did not make this transition despite an overwhelming need in the industry to effectively remove contaminants such as oils with hydrophobic functional groups from the waste stream. To further establish the non-obviousness of the claimed invention, I submit herewith a brief summary of the state of the capsule manufacturing from the time of the '408 Patent. In or about 1993, I made presentations and/or demonstrations, of the invention fairly disclosed in the '408 Patent, to soft gelatin capsule manufacturers including Pharmavite, Banner and R.P. Scherer, the latter two being the largest manufacturers of such capsules in the world.

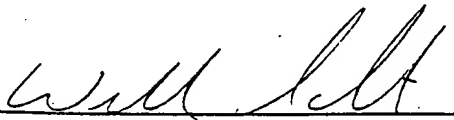
From that time until the present application, no soft gelatin capsule manufacturer to my knowledge, including those highly reputable manufacturers mentioned above, made any advances in the field of waste stream recovery that resemble the present invention, despite their actual knowledge and exposure to the '408 Patent.

22. The nature of the waste gelatin problem addressed by the present invention is of such a magnitude that, if it were obvious to arrive at the present invention from the teachings of the '408 Patent, these leading soft gel manufacturers would have done so. Instead, I am in license negotiations with these companies, further indicating the need and non-obviousness of the present invention over the '408 Patent.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under
5 section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 3 August 01



William J. Schmidt

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

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EXAMINER

ART UNIT

PAPER

20040512

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

The brief does not contain, for each rejection under 35 U.S.C. 103, an argument which specifies the errors in the rejection and, if appropriate, the specific limitations in the rejected claims which are not described in the prior art relied upon in the rejection, and an explanation how such limitations render the claimed subject matter unobvious over the prior art. If the rejection is based upon a combination of references, the argument must explain why the references, taken as a whole do not suggest the claimed subject matter, and shall include, as may be appropriate, an explanation of why features disclosed in one reference may not be properly combined with features disclosed in another reference. A general argument that all the limitations are not described in a single reference does not satisfy the requirements of 37 CFR 1.192(c)(8)(iv).

The brief does not contain a correct concise statement of the issues presented for review as required by 37 CFR 1.192(c)(6).

Appellant is required to comply with provisions of 37 CFR 1.192(c).

To avoid dismissal of the appeal, Appellant must comply with the provisions of 37 CFR 1.192(c) within the longest of any of the following TIME PERIODS: (1) ONE MONTH or THIRTY DAYS, whichever is longer, from the mailing of this communication; (2) within the time period for reply to the action from which appeal has been taken; or (3) within two months from the date of the notice of appeal under 37 CFR 1.191. Extensions of these time periods may be granted under 37 CFR 1.136.

Robert James Popovics

Primary Examiner

Art Unit: 1724

5/12/04

Enclosed: PTO-892